K002850
Page 1 of 4

OCT - 5 2000

510(k) SUMMARY AS REQUIRED BY SECTION 807.92(C)

Submitted by: Mrs. Mitsuko Yoneyama
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Date Submitted: September 11, 2000

Device Identification:

Trade Name: MWO-202 3D Hydraulic Coarse/Fine Micromanipulator
Common Name: Coarse/Fine Micromanipulator
Classification Name: Assisted Reproduction Micromanipulators and Microinjectors (21 CFR, 884.6150)

Predicate Device:

Notice of Final Rule, 63 FR 48428, Docket number 97N-0335

Device Description:

The MWO-202 3D Hydraulic Coarse/Fine Micromanipulator helps coarse and fine positioning of a microtool/micropipette under the microscope and is used in assisted reproduction procedures.

The MWO-202 is an oil hydraulic coarse/fine micromanipulator and composed of two components: the Control Unit and the Drive Unit. The Control Unit is further divided up into two parts: Joystick controller and Separate-type XY Coarse Controller. The Control Unit and the Drive Unit are connected with the oil hydraulic tubing (Teflon tube). This product is controlled by the built in oil hydraulic system and does not require any external power input.

The Drive Unit consists of three sliders, X-, Y-, and Z-axis Unit, and each unit is connected with the oil hydraulic tubing to X-, Y-, and Z-axis Coarse/Fine Control Knobs, respectively, of the Control Unit. Rotating the knobs on the Control Unit moves the respective units on the Drive Unit by the oil pressure.

The X-axis Unit, Y-axis Unit, and Z-axis Unit of the Drive Unit move to the different direction:
X-axis for X-axis Unit (right-left with relation to the microscope);
Y-axis for Y-axis Unit (front-rear with relation to the microscope);
and Z-axis for Z-axis Unit (up-down with relation to the microscope).

Each Coarse Control Knob controls the respective unit of the Drive Unit in coarse movement in the range of 14mm. One rotation of the coarse control knob moves the respective unit by 1.25mm.

Each Fine Control Knob controls the respective unit of the Drive Unit in fine movement in the range of 11mm. One rotation of the fine control knob moves the Unit by 500μm. The maximum movement range, combining the coarse and fine movement range, is 25mm (14mm + 11mm).

The Joystick moves the X-axis Unit and Y-axis Unit simultaneously and enables the fine movement in the X-Y plane. The maximum operating area is a 2mm-diameter circle.

The MWO-202 3D Hydraulic Coarse/Fine Micromanipulator is a component part of a micromanipulator system. A micromanipulator system for ICSI using the MWO-202 requires:
- 1 unit of manipulator mounting adaptor;
- 2 units of MWO-202;
- 2 units of the UT-2 Universal Joint (pre-set to the Drive Unit of the MWO-202) It is used for holding the pipette holder.;
- 2 units of the pipette holder;
- 2 units of microinjector (one for holding pipette and one for injecting pipette);
- 1 holding pipette
- 1 injecting pipette

The role of the MWO-202 in the above micromanipulator setup is to control the position of the micropipettes equipped to the microinjectors.
The examples are as follows:
- coarse positioning of the micropipette into the field of view under the microscope
- coarse positioning of the holding pipette
- coarse positioning of the injecting pipette
- fine positioning of the holding pipette close to the oocyte
- fine positioning of the injecting pipette close to the sperm

- inserting the injecting pipette, equipped with the sperm, into the oocyte

Intended Use:

The MWO-202 3D Hydraulic Coarse/Fine Micromanipulator helps coarse and fine positioning of a microtool/micropipette under the microscope and is used in assisted reproduction procedures.

Substantial Equivalence:

In accordance with the Final Rule on reclassification of Medical Devices Used for In Vitro Fertilization, Narishige Co., Inc. cites 63 FR 48428, Docket number 97N-0335 as support for substantial equivalence.

Technological Characteristic:

The MWO-202 3D Hydraulic Coarse/Fine Micromanipulator is an oil hydraulic coarse and fine micromanipulator which gives positive smooth movement. It can be set up for either right- or left-handed use. The Control Unit and the Drive Unit are connected with the oil hydraulic tubing so that only the Drive Unit is mounted to the microscope leaving the Control Unit independent of the microscope.
Therefore, the Control Unit does not transfer the vibration through the tubing, the Drive Unit, linkage, and to the microtool when controlling the Control Unit. This enables the stable operation.

The Drive Unit is designed compact allowing ample space around the microscope stage.

The Control Unit is designed for one hand easy operation. Each Control Knob is located close together within reach without much moving the hand.

The Joystick allows the movement of the microtool exactly the same way as the hand.

The operating range of each control is summarized in the table below.

Table 7-1

Control Unit	Drive Unit
X-axis Fine Control Knob :	X-axis Unit:
Minimum Graduation	4μm
1 Rotation of the Control Knob	500μm
Maximum Movement Range	11mm
Y-axis Fine Control Knob:	Y-axis Unit:
Minimum Graduation	4μm
1 Rotation of the Control Knob	500μm
Maximum Movement Range	11mm
Z-axis Fine Control Knob:	Z-axis Unit:
Minimum Graduation	4μm
1 Rotation of the Control Knob	500μm
Maximum Movement Range	11mm
Joystick	The maximum operating area is a 2mm-diameter circle.
X-axis Coarse Control Knob :	X-axis Unit:
1 Rotation of the Control Knob	1.25mm
Maximum Movement Range	14mm
Y-axis Coarse Control Knob:	Y-axis Unit:
1 Rotation of the Control Knob	1.25mm
Maximum Movement Range	14mm
Z-axis Coarse Control Knob:	Z-axis Unit:
1 Rotation of the Control Knob	1.25mm
Maximum Movement Range	14mm

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Re: K002850
MWO-202 3-D Hydraulic Coarse/Fine Micromanipulator
Dated: September 11, 2000
Received: September 13, 2000
Regulatory Class: II
21 CFR §884.6150/Procode: 85 MQJ

Dear Mrs. Yoneyama:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002850

Device Name: MWO-202 3D Hydraulic Coarse/Fine Micromanipulator

Indications For Use:

The MWO-202 3D Hydraulic Coarse/Fine Micromanipulator helps coarse and fine positioning of a microtool/micropipette under the microscope and is used in assisted reproduction procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002850

Prescription Use ✓
(Per 21 CFR 801.109)